N.K.



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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|--------|------------|----------------------|-------------------------|------------------|
| 09/960,648 | (| 09/24/2001 | Robert F. Sak | 004122.00006 | 6515 |
| 22907 | 7590 | 01/30/2003 | | | |
| BANNER & WITCOFF | | | | EXAMINER | |
| 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001 | | | WINGOOD, PA | MELA LYNN | |
| WASHING | ON, DC | 20001 | | ART UNIT | PAPER NUMBER |
| | | | | 3736 | |
| | | | | DATE MAILED: 01/30/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. **09/960,648**

Applicant(s)

SAK

Examiner

Pamela Wingood

Art Unit 3736



| | appears on the cover sheet with the correspondence address | | | | | | |
|---|---|--|--|--|--|--|--|
| Period for Reply A SHORTENED STATUTORY PEDIOD FOR BERLY | / IC CET TO EVEIDE O LICENTIAN ED CL | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | | | | | |
| | 136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the | | | | | | |
| - If the period for reply specified above is less than thirty (30) days, a rep | ply within the statutory minimum of thirty (30) days will be considered timely. | | | | | | |
| Failure to reply within the set or extended period for reply will, by statu | will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Ite, cause the application to become ABANDONED (35 U.S.C. § 133). | | | | | | |
| Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ng date of this communication, even if timely filed, may reduce any | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | | |
| _ | This action is non-final. | | | | | | |
| 3) Since this application is in condition for allow closed in accordance with the practice under | wance except for formal matters, prosecution as to the merits is er <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) 💢 Claim(s) <u>1-28</u> | is/are pending in the application. | | | | | | |
| 4a) Of the above, claim(s) | is/are withdrawn from consideration. | | | | | | |
| 5) 💢 Claim(s) <u>1-15</u> | is/are allowed. | | | | | | |
| _ | is/are rejected. | | | | | | |
| cours | is/are objected to. | | | | | | |
| | are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9) \square The specification is objected to by the Exam | niner. | | | | | | |
| 10) The drawing(s) filed on | is/are a) \square accepted or b) \square objected to by the Examiner. | | | | | | |
| | to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| | is: a) \square approved b) \square disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in | | | | | | | |
| 12) \square The oath or declaration is objected to by the | Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgement is made of a claim for fo | reign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some* c) None of: | | | | | | | |
| 1. Certified copies of the priority docume | | | | | | | |
| | nts have been received in Application No | | | | | | |
| Copies of the certified copies of the pri application from the Internation *See the attached detailed Office action for a lis | iority documents have been received in this National Stage al Bureau (PCT Rule 17.2(a)). | | | | | | |
| 14) Acknowledgement is made of a claim for do | | | | | | | |
| a) The translation of the foreign language pro | | | | | | | |
| | emestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | mostic priority drider od 0.0.0. 33 120 drid/or 121. | | | | | | |
| 1) X Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) Paper No(s). | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) | | | | | | |
| 3) X Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 | 6) Other: | | | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuster et al.(404).

Schuster et al. disclose swab for taking a sample from the cervical or vaginal canal, using the distal sampling member (Figs. 1-3, @ 11,13,or 15), removing the sampling member and applying an ethanol based fixative of 70% (Fig. 4, Clm. 5) by inserting the sampler into a container.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (404).

Schuster et al. (404) disclose the limitations above, but do not disclose the claimed percentage of the ethanol based solution. There is no apparent criticality for the claimed percentage, accordingly there is no patentable weight being giving to the claimed percentage.

Varying the percentage of ethanol in the preservative would be obvious. (*Minerals Separation*, *Ltd. v. Hyde*, 242 U.S. 261 (1916).

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (404) in view of Canna.

Schuster et al. (404) disclose the limitations above a device for conducting a cervical Pap smear and the use of the ethanol fixative; however, they do not disclose such a preservative using carbowax.

Canna discloses a Cervical Pap smear device using carbowax as part of the fixative in an analogous art for the purpose of preserving the cells. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Schuster et al. (404) in view of Canna because carbowax is a known fixative for maintaining cell vitality prior to testing. (Col.4).

6. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (404) in view of Hasselbrack.

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Schuster et al. (404) discloses the limitations above but does not disclose spraying the

fixative on the sample.

Hasselbrack disclose the step of spraying a fixative onto a cervical sample in an analogous

art for the purpose of preserving the sample. It would have been obvious to one of ordinary skill

in the art at the time the invention was made to have modified the device of Schuster et al. (404)

as shown by Hasselbrack because spraying the fixative would provide for an even distribution of

the fixative on the cellular sample.

Allowable Subject Matter

7. Claims 1-15 are allowed.

8. Claims 20-27 are objected to as being dependent upon a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and any

intervening claims.

Any questions regarding this application can be addressed to Pamela Wingood who can be

reached on (703)308-2676.

Pamela Winggod

Patent Examiner

January 28, 2003

MAX F. HINDENBUBG

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SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 3700